DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

m2588

VIA FEDERAL EXPRESS

Our Reference: 29-39754

May 4, 1999

Arend Van Vliet, Partner
John G. Visser, Partner
Rock Creek Dairy
29770 East Highway 4
Farmington, California 95230

WARNING LETTER

Dear Messrs. Van Vliet and Visser :

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 21, 1999, by Food and Drug Administration (FDA) Investigator Karen L. Robles has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On March 10, 1999, you sold a bull calf (identified by USDA laboratory report number 384800) for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed neomycin in the kidney at 16.00 parts per million (ppm). Presently, the tolerance level for neomycin in the uncooked edible kidney tissues of cattle is 7.2 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are inadequate and medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

2. You lack an adequate system for determining the medication status of animals you offer for slaughter.

3. You lack an adequate inventory system for determining the quantities of drugs used to medicate yours cows and calves.

You are adulterating the drugs oxytetracycline hydrochloride and neomycin contained in the product Calf Formula #5 which you use to medicate your calves within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Calf Formula #5 prescribes a thirty day withdrawal period prior to slaughter for food use. Your practice of administering Calf Formula #5 to bull calves and an inadequate withdrawal period presents a possibility that illegal residues will occur and is likely the cause of the illegal residue found in the calf you sold for food use.

Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a calf buyer where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of September 16, 1993, through October 8, 1996, your firm offered three calves and two cows for food use which were found to contain illegal drug residues. During this same period you sold one calf which was found to be CAST positive due to the possible presence of harmful levels of antibiotics. An inspection was conducted of your dairy on December 6, 1989. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Regulatory Letter, dated March 1, 1990, was sent to you as a result of the violations found during the inspection. Another inspection of your dairy was conducted on December 17, 1996. During the inspection you were warned again that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated January 31, 1997, was sent to you as a result of the violations found during the inspection. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, CA 95814.

Sincerely yours,

Robert B. Johnson for

Patricia Ziobro
District Director
San Francisco District

cc: [redacted]